

## REMARKS

Claims 1-11 are pending in this application.

### The rejection of claims 1-3, 5-9 and 11 under 35 U.S.C. § 102(a)

The Examiner has maintained the rejection of claims 1-3, 5-9 and 11 under 35 U.S.C. § 102(a) as anticipated by Geusens et al., J of Clin Densitometry, 2001;4:389-394. According to the Examiner, Geusens discloses the case history of an 18-year old boy treated with intravenous pamidronate (a biphosphanate) for extreme back pain resulting from multiple vertebral fractures. Applicant respectfully traverses this rejection.

Claim 1, the only independent claim, reads:

A method of treating chronic spinal mechanical pain which comprises intravenously administering to a subject in need of chronic spinal mechanical pain relief an effective amount for relieving spinal mechanical pain of a bisphosphonate. (emphasis added)

The specification defines "chronic spinal mechanical pain" to mean "any back pain lasting more than twelve weeks which is not caused by cancer, or an osteoporotic compression fracture" (specification, page 7, lines 15-16). The Examiner was not persuaded by Applicant's argument that Geusens does not disclose or suggest treating chronic spinal mechanical pain, as the term is defined in the specification, because the patient disclosed in Geusens has osteoporotic vertebral compression fractures. According to the Examiner, "it is clear from Geusens that the patient suffered from osteoporosis but it is not conclusive whether that patient has compressive fracture" (Office Action, page 3).

This response is accompanied by a Declaration of Dr. Marco Pappagallo Under 37 C.F.R. 1.132 ("Pappagallo Declaration"). Dr. Pappagallo is the inventor of the instant invention, the Director of Pain Medicine Research and Development at Mount Sinai School of Medicine, and a Professor of Anesthesiology at Mount Sinai School of Medicine. Dr. Pappagallo completed his neurology residency in 1990 and his pain medicine fellowship in 1993. Dr. Pappagallo has practiced as an attending physician since 1993.

According to Dr. Pappagallo, the patient described in Geusens has osteoporotic vertebral compression fractures. See Pappagallo Declaration, paragraphs 9-13. The diagnosis of vertebral

compression fractures is based on the patient's X-rays, which show a decrease in vertebral body height. *See id.* at paragraph 13; Geusens, page 391, Figure 1. The diagnosis of osteoporotic vertebral compression fractures is based on the patient's history of osteoporosis, no history of trauma to account for the fractures, and the patient's X-rays, which show fractures limited to the vertebral bodies. *See* Pappagallo Declaration, paragraph 13; Geusens, page 389-393. Thus, Geusens discloses the treatment of an osteoporotic compression fracture. Such a fracture does not fall within the definition of chronic spinal mechanical pain. Claims 1-3, 5-9 and 11 are directed to the treatment of chronic spinal mechanical pain. Accordingly, this rejection should be withdrawn.

The rejection of claims 1, 4 and 10 under 35 U.S.C. § 103(a)

The Examiner has maintained the rejection of claims 1, 4 and 10 under 35 U.S.C. § 103(a) as obvious over Urban et al., Society for Neuroscience Abstracts, 2001;27(1):1326 in view of U.S. Patent No. 6,676,970 (Bader). According to the Examiner, Urban discloses that zoledronate (a bisphosphonate) produces an anti-allodynic effect in rats, and Bader discloses parental zoledronate preparations. The Examiner contends that it would have been obvious to one of ordinary skill in the art to use intravenous zoledronate to treat pain based on these references. Applicant respectfully traverses this rejection.

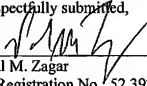
Urban discloses treating bone cancer-induced pain in rats using zoledronate. Bader discloses treating osteoporosis using bisphosphonates (see, e.g., Bader at column 3, lines 46-54; column 5, lines 19-21). Claims 1, 4 and 10 are directed to the treatment of chronic spinal mechanical pain. Bone cancer pain (Urban) is excluded from the definition of chronic spinal mechanical pain ("chronic spinal mechanical pain" means "any back pain lasting more than twelve weeks which is not caused by cancer, or an osteoporotic compression fracture," specification, page 7, lines 15-16). Bader does not disclose using bisphosphonates to treat pain. Thus, no combination of Urban and Bader discloses or suggests treating chronic spinal mechanical pain, i.e., back pain lasting more than twelve weeks which is not caused by cancer or an osteoporotic compression fracture. Accordingly, this rejection should be withdrawn.

Conclusion

No new matter has been introduced. The pending claims are all believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If any points remain in question, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Dated: June 5, 2007

Respectfully submitted,

By   
Paul M. Zagar

Registration No.: 52,392  
DARBY & DARBY P.C.  
P.O. Box 5257  
New York, New York 10150-5257  
(212) 527-7700  
(212) 527-7701 (Fax)  
Attorneys/Agents For Applicant